UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' RESPONSE TO DEFENDANTS DEY, INC. AND DEY, L.P.'S LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT AND STATEMENT OF ADDTIONAL UNDISPUTED FACTS IN OPPOSITION TO DEY'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules of this Court, Plaintiffs hereby submit their Response to Dey, Inc. and Dey, L.P.'s (collectively, "Dey") Statement of Undisputed Material Facts in Support of Dey's Motion for Partial Summary Judgment and Statement of Additional Undisputed Facts in Opposition to Dey's Motion for Partial Summary Judgment. In the responses that follow, any statement submitted by Dey that Plaintiffs do not dispute is undisputed solely for purposes of Plaintiffs' response to Dey's motion for partial summary judgment. Plaintiffs reserve the right to dispute any such statement of fact for purposes of trial. *See* LR 56.1.

I. DEY'S SUBJECT DRUGS

1. The First Amended Complaint in this action ("Am. Compl.") alleges claims against Dey arising from reimbursement by Medicaid and Medi-Cal to providers for dispensing varying dosages, concentrations, and sizes of drugs sold under 65 National Drug Codes (NDCs). (Reid Decl., Ex. 1; Robben Decl., Ex. 1.)

   Plaintiffs' Response: Undisputed.

2. The drugs listed in Exhibit C to the Amended Complaint are sold under a number of NDCs. NDCs are codes that uniquely identify the drug by labeler, active ingredient, and package size. (*See Id.*; Reid Decl., Ex. 2.)

Plaintiffs' Response: Undisputed.

3. The following are the NDCs for the drugs listed in Exhibit C to the Amended Complaint:

Subject Drug	**Strength/ Package Size**	**NDC**
Acetylcysteine	10% vial	49502-0181-04
Acetylcysteine	10% vial	49502-0181-10
Acetylcysteine	10% vial	49502-0181-30
Acetylcysteine	20% vial	49502-0182-04
Acetylcysteine	20% vial	49502-0182-10
Acetylcysteine	20% vial	49502-0182-30
Albuterol Sulfate	.083%, 3ml, 25s	49502-0697-03
Albuterol Sulfate	.083%, 3 ml, 30s	49502-0697-33
Albuterol Sulfate	.083%, 3ml, 60s	49502-0697-60
Albuterol Sulfate	.083%, 3ml, 25s	49502-0697-24
Albuterol Sulfate	.083%, 3 ml, 30s	49502-0697-29
Albuterol Sulfate	.083%, 3ml, 60s	49502-0697-61
Albuterol Sulfate	.5%, 20 ml	49502-0105-01
Albuterol Sulfate	.5%, 20 ml	49502-0196-20
Albuterol Sulfate	17g	49502-0303-27
Albuterol Sulfate	17g	49502-0303-17
Albuterol Sulfate	17g, 90 mcg	49502-0333-17
Albuterol Sulfate	17g	49502-0333-27
Albuterol Sulfate	2 mg, 5 ml	49502-0795-16
Alprazolam	0.5 mg	49502-0406-05
Alprazolam	1 mg	49502-0407-01
Atenolol	50 mg	49502-0400-01
Atenolol	100 mg	49502-0401-01
Cromolyn Sodium	20 mg, 2 ml, 60s	49502-0689-02
Cromolyn Sodium	20 mg, 2 ml, 120s	49502-0689-12
Cromolyn Sodium	20 mg, 2 ml, 60s	49502-0689-61
Duoneb	2.5-0.5 mg, 3 ml	49502-0672-30
Duoneb	2.5-0.5 mg, 3 ml	49502-0672-60
Epipen	0.3 mg	49502-0500-01
Epipen	0.3 mg	49502-0500-02
Epipen	0.15 mg	49502-0501-01
Epipen	0.15 mg	49502-0501-02

Hydrocodone	5/500 tab	49502-0415-01
Hydrocodone	5/500 tab	49502-0415-05
Hydrocodone	7.5/750 TB	49502-0416-01
Hydrocodone	7.5/650 TB	49502-0417-01
Ipratropium Bromide	.02%, 2.5 ml, 25s	49502-0685-03
Ipratropium Bromide	.02%, 2.5 ml, 30s	49502-0685-33
Ipratropium Bromide	.02%, 2.5 ml, 60s	49502-0685-60
Ipratropium Bromide	.02%, 2.5 ml, 25s	49502-0685-24
Ipratropium Bromide	.02%, 2.5 ml, 30s	49502-0685-29
Ipratropium Bromide	.02%, 2.5 ml, 60s	49502-0685-61
Ipratropium Bromide	0.03%	49502-0786-30
Ipratropium Bromide	0.06%	49502-0786-15
Metaproterenol Sulfate	0.60%	49502-0676-03
Metaproterenol Sulfate	0.60%	49502-0676-24
Metaproterenol Sulfate	0.40%	49502-0678-03
Metaproterenol Sulfate	0.40%	49502-0678-24
Piroxicam	20 mg	49502-0403-01
Sodium Chloride	3% vial	49502-0640-15
Sodium Chloride	0.45% vial	49502-0820-03
Sodium Chloride	0.45% vial	49502-0820-05
Sodium Chloride	0.9% vial	49502-0830-03
Sodium Chloride	0.9% vial	49502-0830-05
Sodium Chloride	0.9% vial	49502-0830-15
Sodium Chloride	0.9% vial	49502-0830-50
Theophylline	100 mg	49502-0431-01
Theophylline	200 mg	49502-0432-01
Theophylline	200 mg	49502-0432-05
Theophylline	300 mg	49502-0433-01
Theophylline	300 mg	49502-0433-05
Triazolam	0.125 mg	49502-0412-01
Triazolam	0.25 mg	49502-0413-01
Water for Inhalation Vial		49502-0810-03
Water for Inhalation Vial		49502-0810-05

(Reid Decl., Ex. 1.)

Plaintiffs' Response: Undisputed.

II. CALIFORNIA HAS NOT CALCULATED "OVERPAYMENTS" FOR ALL OF THE DRUGS LISTED IN THE COMPLAINT

4. Although Exhibit C to the Amended Complaint lists 65 NDCs, California's expert, Dr. Jeffrey J. Leitzinger, performs "overpayment" calculations for only 28 of the Dey NDCs listed in the Amended Complaint. (*See* Reid Decl., Ex. 3; Reid Decl., Ex. 1.)

Plaintiffs' Response: Undisputed.

5. Dr. Leitzinger performs his calculations for the period from January 1, 1994 through December 31, 2004. (*See* Reid Decl., Ex. 3, at ¶ 5(a).)

Plaintiffs' Response: Undisputed.

6. The following are the 28 NDCs for the Subject Drugs analyzed by Dr. Leitzinger:

Subject Drug	**Strength/ Package Size**	**NDC**
Acetylcysteine	10%	49502-0181-04
Acetylcysteine	10%	49502-0181-10
Acetylcysteine	10%	49502-0181-30
Acetylcysteine	20%	49502-0182-04
Acetylcysteine	20%	49502-0182-10
Acetylcysteine	20%	49502-0182-30
Albuterol Sulfate	.083%, 3ml, 25s	49502-0697-03
Albuterol Sulfate	.083%, 3 ml, 30s	49502-0697-33
Albuterol Sulfate	.083%, 3ml, 60s	49502-0697-60
Albuterol Sulfate	.083%, 3ml, 25s	49502-0697-24
Albuterol Sulfate	.083%, 3 ml, 30s	49502-0697-29
Albuterol Sulfate	.083%, 3ml, 60s	49502-0697-61
Albuterol Sulfate	.5%, 20 ml	49502-0105-01
Albuterol Sulfate	.5%, 20 ml	49502-0196-20
Albuterol Sulfate	17g	49502-0303-27
Albuterol Sulfate	17g	49502-0303-17
Albuterol Sulfate	17g, 90 mcg	49502-0333-17
Cromolyn Sodium	20 mg, 2 ml, 60s	49502-0689-02
Cromolyn Sodium	20 mg, 2 ml, 120s	49502-0689-12
Cromolyn Sodium	20 mg, 2 ml, 60s	49502-0689-61
Ipratropium Bromide	.02%, 2.5 ml, 25s	49502-0685-03
Ipratropium Bromide	.02%, 2.5 ml, 30s	49502-0685-33
Ipratropium Bromide	.02%, 2.5 ml, 60s	49502-0685-60
Ipratropium Bromide	.02%, 2.5 ml, 25s	49502-0685-24
Ipratropium Bromide	.02%, 2.5 ml, 30s	49502-0685-29

Ipratropium Bromide	.02%, 2.5 ml, 60s	49502-0685-61
Metaproterenol Sulfate	0.60%	49502-0676-03
Metaproterenol Sulfate	0.60%	49502-0676-24

(Reid Decl., Ex. 3, at Exhibit 3.)

Plaintiffs' Response: Undisputed.

7. Professor Matthew Perri, California's marketing expert as to Dey, testified that he had been informed by California's counsel that the Dey drugs "of primary interest" in the case were acetylcysteine, albuterol sulfate, cromolyn sodium, ipratropium bromide, metaproterenol, and EpiPen. (Reid Decl., Ex. 4, at 66:17-20, 68:13-20 & Exhibit 20.) California's counsel subsequently informed him that EpiPen was not going to be at issue in this case. (Reid Decl., Ex. 4, at 72:19 -74:6.)

Plaintiffs' Response: Undisputed.

III. PRICING OF THE SUBJECT DRUGS

A. Dey's Prices at Launch

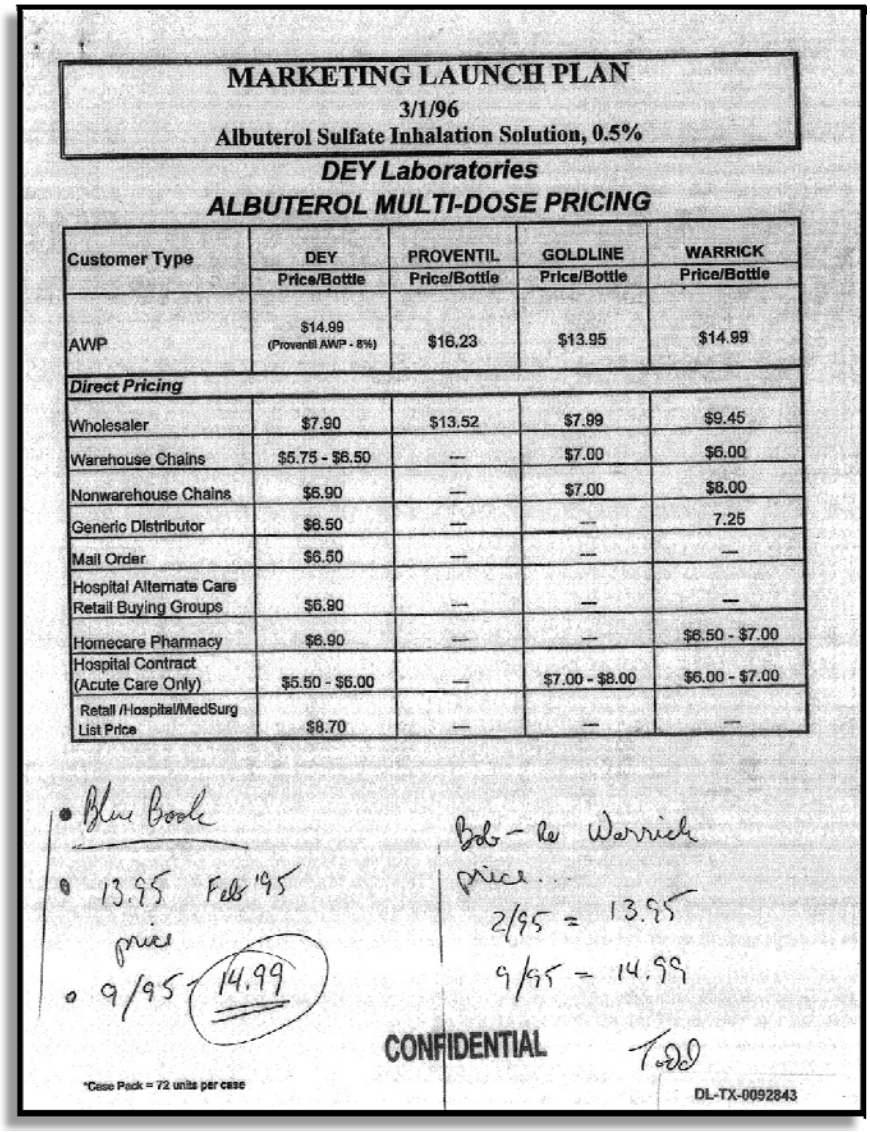
8. At launch, pricing for a generic, like Dey's albuterol, is set in relationship to the brand AWP. (Reid Decl., Ex. 5, at 129:22-130:11.)

Plaintiffs' Response: Disputed. Objection, incompetence of the witness to testify as an expert. Dey's SOF 8 cites to the deposition testimony of Pam Marrs, the Chief Financial Officer of Dey. This "fact" appears to be a general statement about pricing generics. Pam Marrs has not been qualified as an expert to testify about pricing generics. Since SOF 8 is stated in terms of how Dey prices generics, it is improperly worded as a general statement of fact and presupposes that Pam Marrs has the authority and competence to comment on appropriate pharmaceutical industry standards for the pricing of generic drugs.

If Marrs' testimony is permitted, Plaintifs dispute this fact because Plaintiffs note that the actual prices for Dey's generic products at launch did not have a defined relation to brand prices. To the extent Dey uses the terms "pricing" to mean its reported AWPs, Plaintiffs do not dispute that Dey sometimes set its products' AWPs by reference to the brand AWP. Plaintiffs note that

Dey admits by this fact that it did not set the AWPs of its products at their actual average wholesale prices (which Plaintiffs do not dispute).

With regard to Dey setting its products' AWPs in relation to the brand, Plaintiffs dispute that Dey did this on all occasions, particularly when competing generic products were already on the market. In the case of Dey's Albuterol Sulfate solution 0.5% launch dated March 1, 1996, Dey set the AWP by matching its generic competition. The brand Proventil had an AWP of $16.23 per bottle with Warrick's AWP at $14.99.



MARKETING LAUNCH PLAN
3/1/96
Albuterol Sulfate Inhalation Solution, 0.5%
DEY Laboratories
ALBUTEROL MULTI-DOSE PRICING

Customer Type	DEY Price/Bottle	PROVENTIL Price/Bottle	GOLDLINE Price/Bottle	WARRICK Price/Bottle
AWP	$14.99 (Proventil AWP - 8%)	$16.23	$13.95	$14.99
Direct Pricing				
Wholesaler	$7.90	$13.52	$7.99	$9.45
Warehouse Chains	$5.75 - $6.50	—	$7.00	$6.00
Nonwarehouse Chains	$6.90	—	$7.00	$8.00
Generic Distributor	$6.50	—	—	7.25
Mail Order	$6.50	—	—	—
Hospital Alternate Care Retail Buying Groups	$6.90	—	—	—
Homecare Pharmacy	$6.90	—	—	$6.50 - $7.00
Hospital Contract (Acute Care Only)	$5.50 - $6.00	—	$7.00 - $8.00	$6.00 - $7.00
Retail /Hospital/MedSurg List Price	$8.70	—	—	—

• Blue Book
• 13.95 Feb '95 price
• 9/95 - 14.99

Bob - Re Warrick price...
2/95 = 13.95
9/95 = 14.99

CONFIDENTIAL

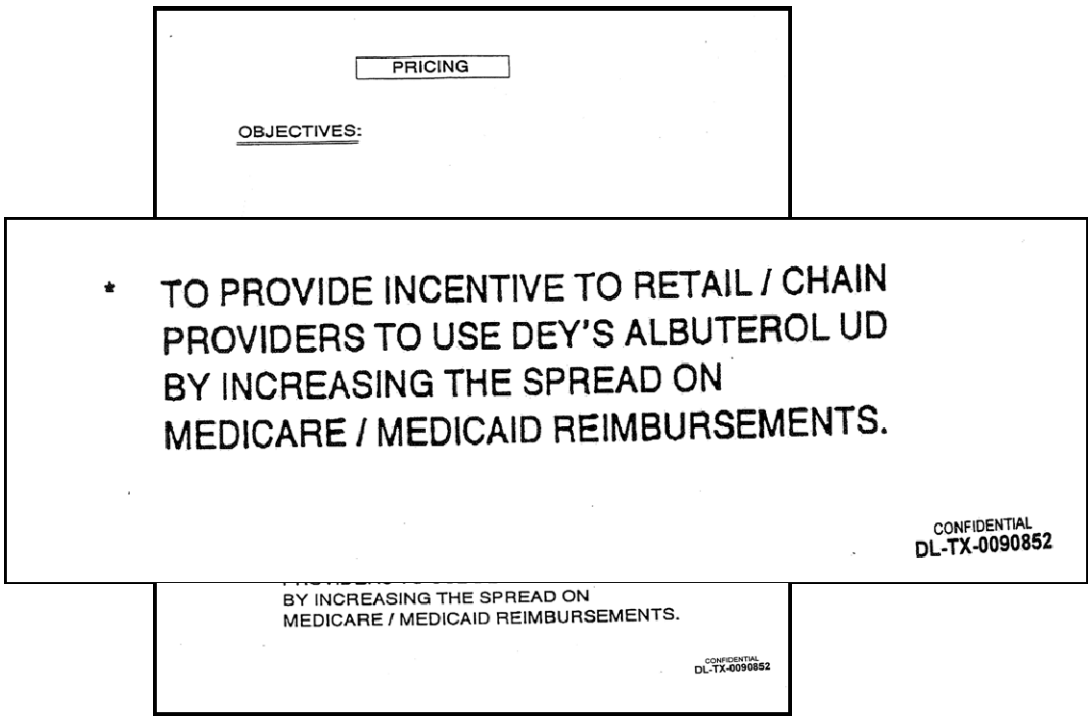
Todd

*Case Pack = 72 units per case

DL-TX-0092843

(Declaration of Rita Hanscom ("Hanscom") Decl., at Ex. 1 (DL-TX-0092843).) The handwritten notes below state: "Bob – Re Warrick price. 2/95 = 13.95 9/95 = 14.99 Todd." Dey therefore set its AWP at Warrick's price of $14.99. To further illustrate Dey's strategies for increasing the spread, the chart also shows that Dey's actual wholesale prices range from $5.60 to $8.70, less than each of Warrick's and Goldline's actual wholesale prices, thereby providing Dey's customers with the biggest spread so as to maximize their reimbursement.

Dey established its AWP pricing strategies in February 1992. A memo from Robert Mozak to Pam Marrs, Charles Rice, and Jean-Pierre Termier reveals Dey's focus on increasing its spreads by lowering acquisition costs more than AWPs, with the objective of providing incentives to providers to use its product by increasing the spread on Medicare and Medicaid reimbursements.


PRICING

OBJECTIVES:

* TO PROVIDE INCENTIVE TO RETAIL / CHAIN PROVIDERS TO USE DEY'S ALBUTEROL UD BY INCREASING THE SPREAD ON MEDICARE / MEDICAID REIMBURSEMENTS.

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BY INCREASING THE SPREAD ON
MEDICARE / MEDICAID REIMBURSEMENTS.

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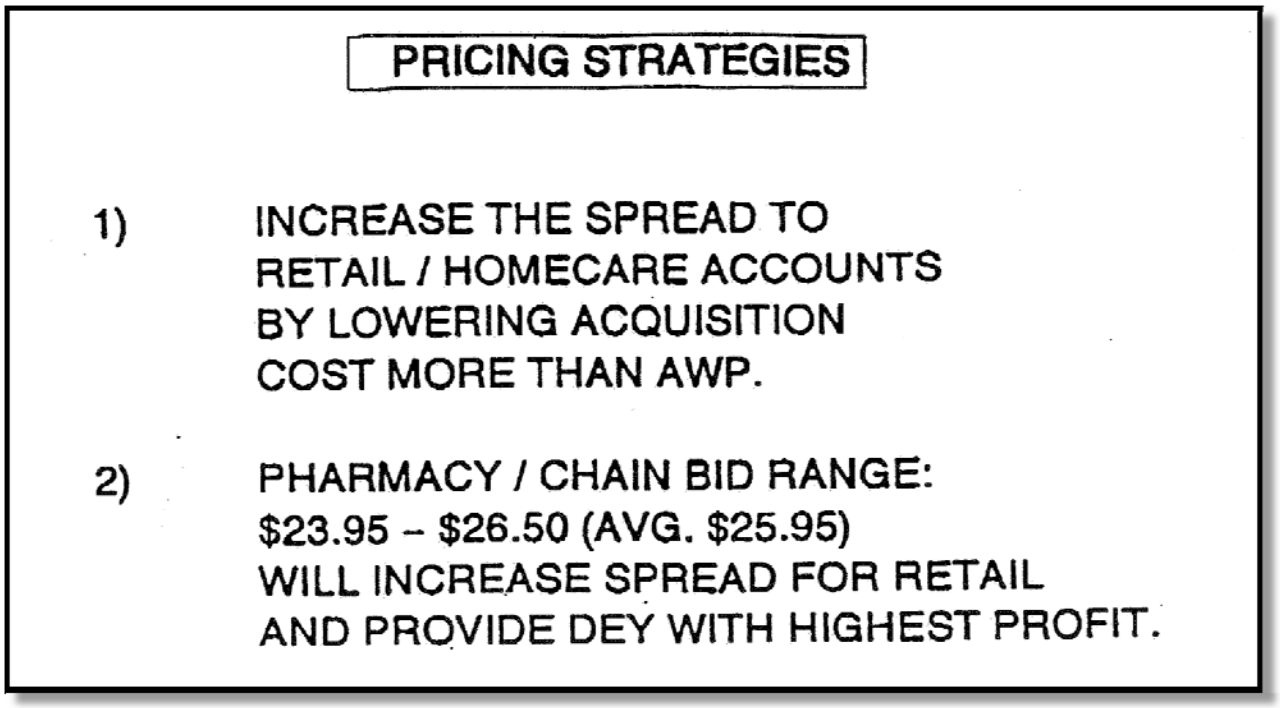
DL-TX-0090852

(Hanscom Decl. Ex. 2 (3/10/05 Marrs Dep.), at Ex. 9.)

In the same memo, Dey sets out its pricing strategies, to increase the spread by lowering acquisition cost more than AWP, in order to provide Dey with the highest profit.


PRICING STRATEGIES

1) INCREASE THE SPREAD TO RETAIL / HOMECARE ACCOUNTS BY LOWERING ACQUISITION COST MORE THAN AWP.

2) PHARMACY / CHAIN BID RANGE: $23.95 – $26.50 (AVG. $25.95) WILL INCREASE SPREAD FOR RETAIL AND PROVIDE DEY WITH HIGHEST PROFIT.

(Hanscom Decl. Ex. 2 (3/10/05 Marrs Dep.), at Ex. 9.)

9. Dey's practice of establishing AWPs for the Subject Drugs at a percentage lower than the therapeutically equivalent brand AWPs was consistent with what Dey believed to be the industry practice. (Reid Decl., Ex. 6, at 460:2-8.)

Plaintiffs' Response: Plaintiffs dispute these facts and incorporate response 8, above. By way of further answer, Plaintiffs state that there is no consistent "industry practice" of setting generic AWPs at a set percentage below the brand. Plaintiff's offer the following facts to dispute Defendant's assertion: OIG reported many instances of generic AWPs which were higher than the brand, sometimes three times higher than the brand AWP. And, "[a]fter factoring in manufacturers rebates, the program paid more than five to eight times more for generics than brand products." (Hanscom Decl. Ex. 3 (OIG Report, "The Impact of High-Priced Generic Drugs on Medicare and Medicaid," July 1998), at ii.)

Therefore, Plaintiff's dispute that there was any generally accepted industry practice, and dispute that Dey could or did price its products consistent with what it *alleges* was industry practice.

10. Ed Edelstein of First Databank informed Dey that a generic AWP must be at least 10% lower than the corresponding brand AWP in order to be listed as such by First DataBank. (Reid Decl., Ex. 5, at 129:22-131:14; Reid Decl., Ex. 7, at 731:17-24.)

Plaintiffs' Response:

Plaintiffs dispute this fact. Plaintiffs object that Dey's offered evidence contains inadmissible hearsay. Dey's SOF 10 relies on the deposition testimony of Pam Marrs and Robert Mozak. Both Marrs and Mozak refer to what Ed Edelstein of First DataBank allegedly said. Dey's use of this fact is to establish what FDB said. It is offered for the truth of the statement, that FDB required generics to be 10% lower than the brand to be published by FDB. If offered to prove FDB's policy that generics must be 10% lower, this is inadmissible hearsay. If offered to prove how a generic must be priced, this is inadmissible hearsay. If offered to prove Dey obtained from FDB the "10% rule," this is inadmissible hearsay.

Plaintiffs further dispute Defendant's asserted fact. Patricia Kay Morgan, designated as the person most knowledgable from First DataBank, testified that FDB did not have a 10% rule and had never used a 10 percent rule. (Hanscom Decl. Ex. 4 (11/13/02 Morgan Dep.) at 58:24–59:23.)

11. According to Patricia Kay Morgan, former Manager of Editorial Services at First DataBank, there was a "perception in the industry" that a generic drug had to be priced at least 10 percent less than the brand price. (Reid Decl., Ex. 8, at 21:4-18.)

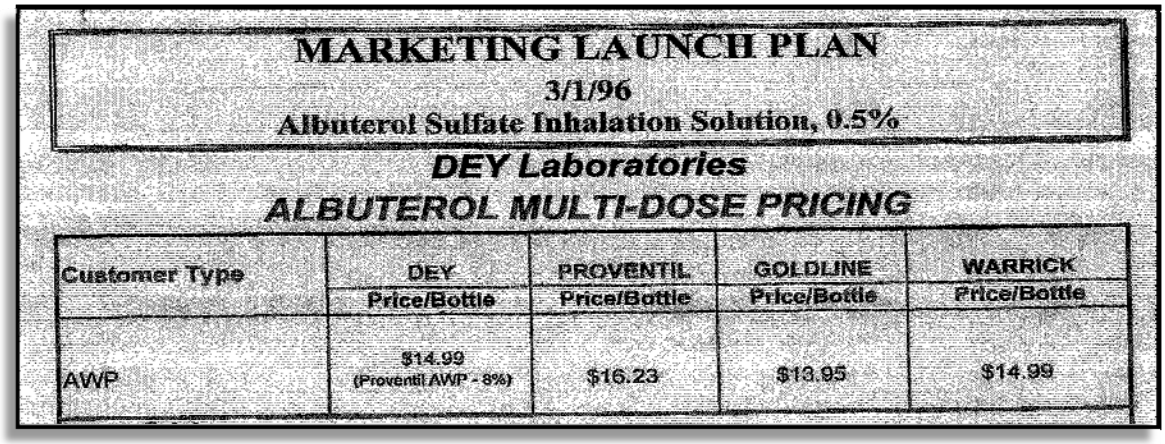
Plaintiffs' Response: Plaintiffs object that this witness is not competent and has not been qualified as an expert to testify on industry practice or on what was *perceived* in the industry; hence, the statement lacks proper foundation. Ms. Morgan is testifying to an industry standard, that there was a "perception" in the industry" about pricing generics at 10% less than the brand.

Ms. Morgan was a manager of a publishing company. There is no showing that Ms. Morgan has the requisite expertise to testify about the pharmaceutical industry standards or pricing perceptions in the industry. She may testify about what First DataBank did, or First DataBank's perceptions, but the proffered testimony exceeds her qualifications.

Plaintiffs incorporate by reference their response to SOF 10 above, as it states evidence to dispute the existence of a "10% rule" at FDB. Plaintiffs further incorporate their response to SOF 8, above, which shows that the AWP for Dey's Albuterol was priced at the same amount as that of Warrick, both of which were only 8% below the brand AWP.

12. Accordingly, Dey set its AWPs for its generic drugs at approximately 10% of the brand AWP and left that price unchanged. (Reid Decl., Ex. 5, at 131:8-132:12; Reid Decl., Ex. 9.)

Plaintiffs' Response: Plaintiffs note Dey admits it did not set its AWP as an average of its wholesale prices. Plaintiffs further note that Dey apparently means that it set its AWP at approximately 10% below the brand AWP, not at "10% of the Brand AWP." Plaintiffs dispute that Dey set its AWPs at 10% of brand or that it set them at 90% of the brand AWPs. Plaintiffs offer the following evidence to dispute Defendant's asserted facts. At launch, Dey set its Albuterol multi-dose at 7.6% less than the brand AWP in order to compete with Warrick which had set its generic AWP at $14.99. The brand AWP for Proventil was $16.23. Because Warrick had set its AWP at $14.99, Dey copied Warrick and set Dey's AWP the same as Warrick's. *See* the Launch Plan below. (Hanscom Decl. Ex. 1 (DL-TX-0092843).)



MARKETING LAUNCH PLAN
3/1/96
Albuterol Sulfate Inhalation Solution, 0.5%
DEY Laboratories
ALBUTEROL MULTI-DOSE PRICING

Customer Type	DEY Price/Bottle	PROVENTIL Price/Bottle	GOLDLINE Price/Bottle	WARRICK Price/Bottle
AWP	$14.99 (Proventil AWP - 8%)	$16.23	$13.95	$14.99

If Dey had priced its product at "10% [below] the brand AWP," the Dey AWP should have been $14.61. Instead, Dey set its AWP based on Warrick's AWP of $14.99. The Exhibit is the Marketing Launch Plan dated 3/1/96 and indicates Dey's price of $14.99 followed by "(Proventil AWP-8%)." Dey's price is 7.6 % below Proventil's AWP.

Even though Dey states it set its generic AWP below the brand AWP, the evidence indicates Dey set its AWPs based on the competition, regardless of the brand AWP. In Dey's Albuterol Pricing Strategies memo from VP of Sales and Marketing Robert Mozak dated February 24, 1992, Dey's objective for "Competitive Prices" shows Dey's Albuterol is only 8% of the Schering brand product.

COMPETITIVE PRICES:

	AWP	WHOLESALE	DIRECT PHCY.	
SCHERING:	35.50*	29.50*	31.86	NEW 2/1/92
DEY:	32.30	24.95	26.50	
DIFF:	- 8.0%	- 15%	- 17%	

(*See* Hanscom Decl. Ex. 2 (3/10/05 Marrs Dep.), at Ex. 9.)

Plaintiffs also dispute Dey's assertion that once it set an AWP it never changed it. Dey raised its AWP on Euthyrox in order to meet competition. Dey's CEO Charles Rice testified that he ordered the AWP to be raised to match the competition.

> Q. That was the drug that you ordered the AWP increased on to increase the spread, correct?
>
> A. To match the competition, yes.
>
> Q. To increase the spread?
>
> A. To match the competition.
>
> Q. Did you or did you not increase the spread when you increased the AWP on euthyrox?

> A. I matched the spread of the competition by increasing the AWP because an error was made in setting the AWP. We've discussed this before under deposition.
>
> Q. Right, right. It hadn't been set high enough?
>
> A. It was set erroneously.

(Hanscom Decl. Ex. 5 (3/24/03 Rice Dep.) at 588:11-24.)

Nineteen additional examples of Dey changing the AWPs on its products are set forth in the letter from Dey's Executive Vice President of Sales and Marketing Robert Mozak dated July 18, 2000. (Hanscom Decl. Ex. 6 (DEY-BO-18892-18898).)

13. Dey then set its WAC price for its generics as a percentage off Dey's AWP. (Reid Decl., Ex. 5, at 144:1-4; Reid Decl., Ex. 6, at 486:6-487:6.)

Plaintiffs' Response: Plaintiffs state that this fact is irrelevant and immaterial to the issues in this case, since WAC is not used for reimbursement in California, which Dey knew throughout the relevant time period. Plaintiffs agree that Dey did not set its WAC in relation to actual wholesale prices, but dispute Dey's assertion that it invariably set its WAC in relation to its AWP. Dey often set its WAC as a percentage of the brand's WAC pricing, not as a percentage off Dey's AWP, as seen in Dey's chart below. When Dey launched Albuterol Sulfate Inhalation Solution 0.083% 3 ml 25's in 1992, it set the WAC at 15% below the brand WAC of Schering's Proventil. This chart is from Dey's VP of Sales and Marketing, Robert Mozak, February 25, 1992 Memo on Albuterol pricing strategies which shows competitive prices:

COMPETITIVE PRICES:

	AWP	WHOLESALE	DIRECT PHCY.	
SCHERING:	35.50*	29.50*	31.86	NEW 2/1/92
DEY:	32.30	24.95	26.50	
DIFF:	– 8.0%	– 15%	– 17%	

(Hanscom Decl. Ex. 2 (3/10/05 Marrs Dep.), at Ex. 9.)

See also the memo from Dey's Cindy Daulong on October 25, 1995, stating "I explained that our WAC was not tied to our AWP…" (Hanscom Decl. Ex. 7 (2/19/03 Collie Dep.), Ex. 750 at ¶ 2.)

Further, Defendant's expert David Bradford stated that for Dey products, AWP has no meaningful economic relationship to WAC. (Hanscom Decl. Ex. 8 (5/7/09 Bradford Dep.) at 146:14-148:13.)

14. Figures 2 through 29 of the declaration of Dr. W. David Bradford, Ph.D., show Dey's WACs relative to its AWPs for albuterol, cromolyn, ipratropium, and metaproterenol. (Reid Decl., Ex. 9, at Figs. 2-29.)

Plaintiffs' Response: Plaintiffs incorporate their response to SOF 13, above, and state that this fact is irrelevant and immaterial to the issues in this case. WAC is not used for reimbursement in California, which Dey knew throughout the relevant time period. *See* Carrie

Jackson memo of February 2, 1994 which surveyed California's reimbursement methodology, and which listed all Dey products and how they were reimbursed, stating: "AWP-5%." (Hanscom Decl. Ex. 9 (4/30/02 Mozak Dep.), at Ex. 231.)

15. WAC is Dey's invoice price to wholesalers. (Reid Decl., Ex. 5, at 75:22-76:3, 144:21-145:1; Reid Decl., Ex. 6, at 537:9-15; Reid Decl., Ex. 10, at 29:6-12, 31:14-16; Reid Decl., Ex. 11, at 501:2-17; Reid Decl., Ex. 12, at DL-0050108.)

Plaintiffs' Response: Plaintiffs state that this fact is irrelevant and immaterial to the issues in this case. WAC is not used for reimbursement in California, which Dey knew throughout the relevant time period. Further, Plaintiffs dispute this fact. According to the testimony below, WAC was not a price that was used to buy or sell Dey's drugs. The term "invoice price" has little meaning as a price since it does not include discounts, chargebacks, fees, and allowances. Dey's Senior Manager of Contracts, Russell Johnston, was evasive when he was asked about Dey's WAC price, declining to say it was the cost, or that it was the selling price, rather, it was an invoice price. (Hanscom Decl. Ex. 10 (12/11/08 Johnston Dep.) at 500:22-502:2.)

It was Dey's practice to set the WAC above the highest contract price, so that Dey's actual prices were nearly always below its reported WACs.

> Q. Would it be fair to say that the way the system was set up, the WAC is specifically designed to be above the highest contract price?
>
> A. Yes.
>
> Q. And there was an understanding at Dey that that's what the WAC price was?
>
> A. Yes.

(Hanscom Decl. Ex. 11 (2/24/03 Uhl Dep.) at 320:6-12.)

Moreover, Dey generally waited until its reported WAC prices were 40 - 50% above market prices before it would report a lower WAC. (Hanscom Decl. Ex. 12 (DL-TX-0163785).)

16. As prices for the Subject Drugs decline over time, Dey reduces the WAC for those drugs. (Reid Decl., Ex. 13, at 662:6-12, 823:13-19; Reid Decl., Ex. 5, at 136:16-21; Reid Decl. Ex. 9, at Figs. 2-29.)

Plaintiffs' Response: Plaintiffs state that this fact is irrelevant and immaterial to the issues in this case. WAC is not used for reimbursement in California, which Dey knew throughout the relevant time period. Plaintiffs note that it has been Dey's practice to wait until its reported WAC prices are 40 - 50 % above market prices before it reports a lower WAC. (Hanscom Decl. Ex. 12.) Plaintiffs further note that Dey did not generally reduce its reported AWP when it reduced the reported WAC for one of its products.

17. Dey regularly updated its WACs in a manner that directly reflected underlying pricing activity. (Reid Decl., Ex. 14, at 372:11-20; Reid Decl. Ex. 9, at Figs. 2-29.)

Plaintiffs' Response: Plaintiffs state that this fact is irrelevant and immaterial to the issues in this case. WAC is not used for reimbursement in California, which Dey knew throughout the relevant time period. Plaintiffs dispute this fact. Dey's Director of Marketing, Helen Burnham Selenati, stated in an internal Dey memorandum dated May 30, 1995: "WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement. Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement." (Hanscom Decl. Ex. 13 (10/30/01 Rice Dep.), at Ex. 72.) Moreover, Dey's WACs do not reflect its underlying pricing activity, since the WAC prices that Dey reports for publication do not include the various discounts Dey offers. Russ Johnston confirmed that Dey's WAC prices did not include rebates, prompt pay discounts or administrative fees. (Hanscom Decl. Ex. 10 (12/11/08 Johnston Dep.) at 468:3-11.)

IV. FEDERAL INVESTIGATIONS INTO THE PRICING FOR DEY'S DRUGS

A. HHS-OIG Investigations Into Dey's Albuterol

18. The OIG has published ten reports studying the acquisition cost of Albuterol:

- "Medicare Payments for Nebulizer Drugs" OEI-03-94-00390 (February 1996) (Reid Decl., Ex. 15);
- "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996) (Reid Decl., Ex. 16);
- "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996) (Reid Decl., Ex. 17);
- "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290 (December 1997) (Reid Decl., Ex. 18);
- "Are Medicare Allowances for Albuterol Sulfate Reasonable?" OEI-03-97-00292 (August 1998) (Reid Decl., Ex. 19);
- "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293 (November 1998) (Reid Decl., Ex. 20);
- "Medicare Reimbursement of Albuterol" OEI-03-00-00311 (June 2000) (Reid Decl., Ex. 21);
- "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001) (Reid Decl., Ex. 22);
- "Excessive Reimbursement for Albuterol" OEI-03-01-00410 (March 2002) (Reid Decl., Ex. 23); and
- "Update: Excessive Medicare Reimbursement for Albuterol" OEI-03-03-00510 (January 2004) (Reid Decl., Ex. 24).

Plaintiffs' Response: Plaintiffs note that most of the cited reports related to the Medicare program, and Dey has not shown that Medi-Cal personnel were aware of such reports. Plaintiffs dispute the statement with regard to OEI-03-97-00290 and OEI-03-94-00390, inasmuch as those reports did not examine actual acquisition costs. For example, OIG report #OEI-03-94-00390 examined payments made by the Medicare program for three selected drugs (one of which was Albuterol Sulfate), and compared them to payments made by Medicaid (Reid Decl. Ex. 15 at 1). The entirety of the reports referenced is the best evidence of their contents.

As a result of the instant investigation and litigation, California has learned that, due to the unlawful conduct of Dey and others, the amounts paid by Medi-Cal for Albuterol Sulfate were not based on "acquisition cost," but instead were based on fraudulently reported AWPs that

have no meaningful relationship to providers' estimated acquisition costs. Language in the reports states disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example, "Excessive Medicare Payments for Prescription Drugs" OEI-03-97-00290 (Reid Decl. Ex. 18 at ii), referring to "excessive payments" because " [t]he published AWPs that are currently being used. . . . to determine reimbursement bear little or no resemblance to actual wholesale prices that are available." Plaintiffs further dispute the statement to the extent it implies "government knowledge" of actual average prices generally and currently paid in the market. Inasmuch as the cited reports only determined acquisition costs relative to a small number of transactions, occurring within a narrow time frame, they do not constitute the requisite full disclosure by Dey. Thus, none of the reports, individually or together, could form a workable basis for setting reimbursement rates under the Medi-Cal program. To the extent certain of the reports identified in the statement considered prices paid by the Veterans Administration (VA), FSS (Federal Supply Schedule) prices are not those "generally and currently paid by providers," as required under the regulations relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq., and Medi-Cal. Comparisons between the VA drug purchasing data and Medicaid reimbursement are not useful because Medicaid programs, unlike the VA, do not purchase drugs directly from manufacturers. (Hanscom Decl. Ex. 14 (5/6/09 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.), at 325:22-326:11.)

19. In "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996), the OIG concluded that members of pharmaceutical buying groups could purchase albuterol sulfate for between 56 and 70 percent lower than the $0.43 per milliliter paid by Medicare at the time. (Reid Decl., Ex. 16, at 5.)

Plaintiffs' Response: Plaintiffs do not dispute that in 1996 the Office of Inspector General published a report entitled "A Comparison of Albuterol Sulfate Prices," which noted the prices five buying groups could negotiate. The entirety of the report referenced is the best

evidence of its contents. Plaintiffs do not dispute that in 1996 pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevance of the report to Dey's liability under the California FCA, however. Language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; see, for example, Reid Decl. Ex. 16 at 7, noting such AWPs resulted in payments for nebulizer drugs that were "inappropriately high" as " the median of the published average wholesale price does not reflect the actual wholesale price of albuterol sulfate." Plaintiffs further note that the report focused on Medicare reimbursement rates, and Dey has not shown that it was known to Medi-Cal personnel.

20. In "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996), the OIG concluded that Medicare suppliers could acquire albuterol sulfate as low as $0.12 per milliliter, while the price paid by Medicare was $0.43 per milliliter. (Reid Decl., Ex.17, at 6.)

Plaintiffs' Response: Plaintiffs dispute this fact's relevance and materiality, as it relates to Medicare not Medicaid. Plaintiffs do not dispute that in 1996, the Office of Inspector General published a report entitled "Suppliers' Acquisition Costs for Albuterol Sulfate," or that Dey has paraphrased from that report. The entirety of the report referenced is the best evidence of its contents. Plaintiffs do not dispute that in 1996 pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevancy of the report to Dey's liability under the FCA, however. Language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; see, for example, Reid Decl. Ex. 17 at 9, noting "Medicare's allowances for albuterol sulfate [based on AWP] are excessive" as HCFA had been "unsuccessful in gathering the data to determine EAC."

21. In December, 1997, the OIG reported that the actual average wholesale price for albuterol sulfate, J7620, in 1995 was $0.15, $0.27 lower than the $0.42 average Medicare reimbursement amount for that time. (Reid Decl., Ex. 18, at B-2.)

Plaintiffs' Response: Plaintiffs dispute this fact's relevance and materiality as it relates to Medicare and J code labeled drugs. California disputes that Dey has accurately stated what was reported in the 1997 Office of Inspector General report entitled "Excessive Medicare Payments for Prescription Drugs." The entirety of the report referenced is the best evidence of its contents. Plaintiffs do not dispute that in 1995 pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevancy of the report to Dey's liability under the FCA, however. The language in the report, including its title itself, indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example, Reid Decl. Ex. 18 at ii, noting "excessive payments for prescription drugs" as the " published AWPs that are currently being used. . . for reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs."

22. In August, 1998, the OIG reported that Medicare will pay between 56 and 550 percent more for albuterol than FSS prices available to the VA and up to 333 percent more than some pharmacies pay to acquire albuterol. (Reid Decl., Ex. 19, at 7, 8.)

Plaintiffs' Response: Plaintiffs dispute this fact's relevance and materiality as it relates to Medicare, FSS prices and prices paid by the VA. Plaintiffs do not dispute that in 1998 the Office of Inspector General published a report entitled "Are Medicare Allowances for Albuterol Sulfate Reasonable" or that Dey has paraphrased from that report. The entirety of the report referenced is the best evidence of its contents. Plaintiffs do not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevancy and materiality of this statement to Dey's liability under the FCA, however. The language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example, Reid Decl. Ex. 19 at iv and 6, noting Medicare is making "excessive payments for albuterol sulfate" compared to "actual prices in the marketplace." *See* further the response to SOF 18 above.

23. In November, 1998, the OIG reported that the median price for the Department of Veterans Affairs (the "VA") to purchase albuterol sulfate unit dose was $0.12, while Medicare's median allowable price was $0.47, resulting in a 292 percent spread. (Reid Decl., Ex. 20, at B-1.)

Plaintiffs' Response: Plaintiffs dispute this fact's relevance and materiality as it relates to amounts paid by Medicare and the Department of Veterans Affairs. Plaintiffs do not dispute that in 1998 the Office of Inspector General published a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" or that Dey has paraphrased from that report. Plaintiffs dispute that the report mentions "spread." The entirety of the report referenced is the best evidence of its contents. Plaintiffs do not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevancy and materiality of this statement to Dey's liability under the FCA, however. VA FSS prices are not those "generally and currently paid by providers" as required under the regulations relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq. The language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example, Exhibit 20 at ii, "actual wholesale prices available to physicians and suppliers are often significantly lower than Medicare allowed amounts" and "published AWPs . . . can be many times greater than actual acquisition costs available in the marketplace." *See* further response to SOF 18 above.

B. HHS-OIG Investigations Regarding Dey's Ipratropium

24. The Government has also specifically studied the actual acquisition cost of another of the Subject Drugs, ipratropium bromide, beginning at least as early as 1998, and the working files from the OIG indicate that the OIG also reviewed various prices for Dey's ipratropium. (*See, e.g.*, Reid Decl., Ex. 20.)

Plaintiffs' Response: Plaintiffs dispute this fact's relevance and materiality. Exhibit 20 compares Medicare and Department of Veteran's Affairs drug reimbursement, neither of which is pertinent or relevant to California's Medi-Cal program. Dey is not mentioned in this report.

25. In "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293, the OIG found that the VA's median price for ipratropium bromide was $1.31 per mg, while Medicare's median allowable price was $3.34 per mg, resulting in a 155% difference. (Reid Decl., Ex. 20, at B-1.)

Plaintiffs' Response: Plaintiffs dispute this fact's relevance and materiality. Plaintiffs do not dispute that in 1998 the Office of Inspector General published a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs," or that Dey has paraphrased from that report. The entirety of the report referenced is the best evidence of its contents. Plaintiffs do not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevancy and materiality of this statement to Dey's liability under the FCA. VA FSS prices are not those "generally and currently paid by providers" as required under the regulations relating to reimbursement for drugs under Medicaid, 42 C.F.R. 447.301 et seq. Comparisons between the Veterans Administration (VA) drug purchasing data and Medicaid reimbursement are not useful because the Medicaid program, unlike the VA, does not purchase drugs directly from manufacturers. Rather, Medicaid reimburses providers who purchase drugs from manufacturers, directly or through wholesalers, and who lack the purchasing power of the VA. (*See* Reid Decl. Ex. 20 at i, ii, 2.) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; see, for example, Reid Decl. Ex. 20 at ii ("actual wholesale prices available to physicians and suppliers are often significantly lower than Medicare allowed amounts" and "published AWPs . . . can be many times greater than actual acquisition costs available in the marketplace").

26. In 2001, 2002 and again in 2004, the OIG continued to find and to report that there were large spreads for ipratropium:

- In "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001), the OIG found that a median VA price was $0.84 per milligram, whereas the median Medicare allowable amount was $3.34, creating a spread of 297 percent. The report also found that the median catalog price for ipratropium was $1.53, creating a spread of 118 percent. (Reid Decl., Ex. 22, at 16-17.)

- In "Excessive Medicare Reimbursement for Ipratropium Bromide" OEI-03-01- 00411 (March 2002), the OIG reported that the median Medicare allowable cost for ipratropium bromide was $3.34, while the median VA price for ipratropium bromide was $0.66, resulting in a "spread" of 406 percent. The report also contained a chart, tracking the Medicare allowable amount against the VA prices between 1998 and 2001. The report also found that the median price for ipratropium appearing in wholesale catalogs was $0.82 per milligram, creating a spread of 307 percent between the catalog price and the Medicare allowable amount. (Reid Decl., Ex. 25, at 9-11.)
- In "Update: Excessive Medicare Reimbursement for Ipratropium Bromide" OIG-03-03-00520 (January 2004), the OIG found that Medicaid set a FUL for ipratropium bromide at $1.17 per mg, 65% less than the $3.34 that Medicare pays for the same drug. The median wholesaler price for that same drug was $0.57, and the median GPO price was $0.62. (Reid Decl., Ex. 26, at ii.)

Plaintiffs' Response: Plaintiffs do not dispute that in 2001, 2002 and 2004 the Office of Inspector General published the cited reports, or that Dey has paraphrased from those reports. Plaintiffs dispute that the report mentions "spreads." The entirety of the reports referenced is the best evidence of its contents. Plaintiffs do not dispute that in 2001, 2002 and 2003, pharmacies could buy drugs at discounts from AWP. Plaintiffs do dispute the relevancy and materiality of this statement to Dey's liability under the FCA. Finally, language in the reports themselves indicates disapproval of AWPs that exceeded providers' actual acquisition costs. See, for example, Exhibit 26 at iv, "This report is part of a series of reports on ipratropium bromide that have consistently found that the published average wholesale prices . . . bear little or no resemblance to actual wholesale prices" resulting in the Medicare program losing "progressively more money every year" and paying "excessive reimbursements." (Reid Decl. Ex. 25 at iii.) Plaintiffs further dispute the statement to the extent it implies government knowledge of actual average prices generally and currently paid in the market, inasmuch as the cited reports, insofar as they investigate actual acquisition costs of Dey products, only determined acquisition costs of a small number of transactions occurring within a narrow time frame. Thus none of the reports, individually or together, could form a workable basis for setting reimbursement rates under the

Medicare or Medicaid programs. To the extent certain of the reports identified in the statement consider prices paid by the VA, see Response to SOF 25 above.

27. Kevin Gorospe testified that someone in the pharmaceutical unit at California DHS would have reviewed the HHS-OIG reports. (Reid Decl., Ex. 27, at 409:5-15.)

Plaintiffs' Response: Plaintiffs do not dispute that Dr. Gorospe said someone would have reviewed "those types of documents," but dispute any implication that his statement applies to reports focusing on Medicare. (Hanscom Decl. Ex. 15 (9/22/08 Gorospe Dep.) at 409:10-15.)

V. DEY'S PRICE NOTIFICATION LETTERS

28. Since 1999, Dey sent letters to state Medicaid administrators, including Medi-Cal administrators, in which Dey explicitly described the nature of its published AWPs and WACs when new products were introduced or when prices were changed. (Reid Decl., Ex. 28; Reid Decl., Ex. 29; Reid Decl., Ex. 30; Reid Decl., Ex. 31; Reid Decl., Ex. 32; Reid Decl., Ex. 33; Reid Decl., Ex. 34; Reid Decl., Ex. 35; Reid Decl., Ex. 36; Reid Decl., Ex. 37; Reid Decl., Ex. 38; Reid Decl., Ex. 39.)

Plaintiffs' Response: Disputed. None of the 14 letters Dey submits establish or support SOF 28 asserted by Dey. Plaintiffs direct the Court's attention to the letters themselves. Dey offers these letters to prove Dey "explicitly described the nature of its published AWPs." The letters merely chronicle what the reported AWPs do *not* represent. "As you know, the AWP listed here does not represent any actual price which will be or has been charged or paid for this product." This does not support Dey's fact that the letters "explicitly describe the nature" of its published AWPs. The letters do not contain actual average wholesale prices or wholesaler acquisition costs for any of its drugs. Furthermore two of the letters are internally inconsistent, explaining that once Dey sets an AWP it does not subsequently change it. But three sentences later Dey explains that *it is changing* the AWP due to current conditions in the marketplace." (Reid Decl. Exs. 32, 33.) These contradictory statements do not support Dey's fact that the letters *explicitly describe* the nature of its AWPs.

According to the letters, Dey's alleged practice of not changing its AWPs is consistent with industry practice. Yet, this could not have been consistent with industry practice or understood by state and federal Medicaid regulators, because the cited allegation is not true. In fact, Dey changed its AWP when it was to its competitive advantage, but never to reflect the actual average wholesale prices of its drugs. For example, Dey raised its reported AWP for its drug Euthyrox in order to bring its AWP spread in line with its competitors. (Hanscom Decl. Ex. 16 (11/7/02 Rice Dep.) at 430:6-431:8.) Nineteen additional examples of Dey changing the AWPs on its products can be seen in the letter from Dey's Executive Vice President of Sales and Marketing Robert Mozak dated July 18, 2000, a copy of which is marked as Exhibit 25 (DL-0050108) to the Declaration of Sarah Reid, submitted by Dey in support of its motion. Two of the letters submitted by Dey in support of its SOF 28 directly contradict this statement, by baldly stating: "DEY has chosen to change the AWP on these products at this time principally due to current conditions in the marketplace." (Reid Decl. Exs. 116, 120.) Moreover, each of these letters, presenting misrepresentations of fact to federal and state Medicaid regulators, fail to provide the government agencies to which they are addressed any information concerning actual average wholesale prices or wholesaler acquisition costs for any of its drugs. In this regard, Dey's Senior Manager of Contracts Russell Johnston, who had the responsibility of reporting Dey's AWPs and WACs, testified concerning these letters to Medicaid Administrators, and didn't know what an estimate of average wholesale prices was. (Hanscom Decl. Ex. 10 (12/11/08 Johnston Dep.), at 462:13-464:3.) See also Dey's August 10, 1999, memorandum to Dey employee Russell Johnston, explaining that two different form letters were to be sent to Medicaid Administrators, one containing Dey's reported AWPs and WACs to be sent to states whose Medicaid agency bases reimbursement on WAC, and another containing just Dey's

reported AWPs to be sent to states whose Medicaid agencies reimburse based upon AWP. AWP states, such as California, didn't receive the letter showing the lower WAC price. (Hanscom Decl. Ex. 17 (12/11/08 Johnston Dep.), at Ex. 53.)

29. For example, in one such letter dated August 10, 1999, Robert Mozak, Dey's Executive Vice President for Sales and Marketing, wrote to state Medicaid administrators as well as regional Medicare benefits administrators, apprising them of a new NDC number for Dey's Albuterol Sulfate Inhalation Solution 0.5%. (Reid Decl. Ex. 30.)

Plaintiffs' Response: Disputed. There is no evidence that this letter went to state Medicaid administrators. Exhibit 17 to the Hanscom Declaration shows a memo from Todd Galles to Russ Johnston on August 10, 1999 explaining there are *two letters:* one went to WAC states, and the other to AWP states. Plaintiffs dispute that the letter in Defendant's Exhibit 30 was the letter sent to California's Medi-Cal.

30. The letter describes Dey's WAC as follows:

> As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid.

(Reid Decl., Ex. 30 (emphasis in original).)

Plaintiffs' Response: Objection, not relevant and immaterial. California does not reimburse on WAC.

31. The letter goes on to describe AWP as follows:

> Further, as you also know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

(Reid Decl., Ex. 30 (emphasis in original).)

Plaintiffs' Response: Plaintiffs dispute that this letter "describes AWP" as advanced by Dey. Plaintiffs dispute that this letter informed Medi-Cal of the spreads between its reported AWPs and reasonable estimated acquisition costs. Plaintiffs were not informed, and therefore did not approve of Defendant's AWPs. Moreover, as noted above, this letter did not accurately set forth the facts, as Dey raised its reported AWPs when that helped it compete. Further, the letter did not advise Medi-Cal that Dey's AWPs, even at launch, were greatly in excess of anticipated market prices.

As evidence documenting this disputed issue of fact, Plaintiffs note the following deposition of testimony (the pertinent question about Dey is at the end, and follows questions about Mylan and Sandoz, provided for the context):

Dr. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit, was asked if Defendants had ever revealed information about Defendants' AWPs:

> Q. At any time in your career at DHCS have you ever received any communication of any sort from Mylan explaining the differences between the AWPs it reports and providers' actual acquisition costs?
>
> A. Not that I can recall.
>
> Q. At any time in your career at DHCS have you ever received any communication of any sort from Sandoz explaining the differences between the actual acquisition costs for its drugs and Sandoz's reported AWPs?
>
> A. Not that I can recall.

> Q. I won't restate the question each time, but the same question regarding Dey Pharmaceuticals?
>
> A. Not that I recall -- not that I can recall, no.

(Hanscom Decl. Ex. 15 (9/22/08 Gorospe Dep.) at 698:8-699:2.)

32. The letter closes with the following sentence: "If you need additional information, please feel free to contact Todd Galles, Senior Product Manager, at 800-755-5560, ext. 7450." (Reid Decl., Ex. 30.)

Plaintiffs' Response: Objection, lack of relevance and immaterial.

33. Len Terra, Chief of the Medi-Cal Drug Program, was one of the recipients of this letter. (Reid Decl., Ex. 30, at DEY-LABS-0415394.)

Plaintiffs' Response: Disputed. Objection, lack of foundation. There is no evidence that this letter was received. As stated in Plaintiff's response to SOF 29 above, there were two letters prepared by Dey to be sent to Medicaid administrators. The memo from Todd Galles instructs Russ Johnston that the letter with both WAC and AWP prices was to be sent to WAC states and the letter with AWP prices to be sent to AWP states. California is an AWP state. Plaintiffs therefore dispute Defendant's implication that this letter was sent, or its assertion that this letter was received.

Further, Mr. Terra was never asked about this August 10, 1999 letter at his deposition.

34. Todd Galles, the Dey contact person listed on the August 1999 letter discussed above, testified that he had never been contacted by anyone regarding the letter. (Reid Decl., Ex. 40, at 410:1-411:15.)

Plaintiffs' Response: Plaintiffs do not dispute that Mr. Galles testified as indicated.

35. In addition to the general letters, many letters were specifically addressed to Medi-Cal officials, including: (i) a March 16, 1999 letter to Kevin Gorospe, Senior Pharmacy Consultant for Medi-Cal Benefits Branch, introducing the EasiVent Mask; (ii) July 18, 2000 letter to Len Terra, Chief of the Medi-Cal Drug Program, introducing a new Albuterol Inhalation Aerosol, 17g Metered Dose Inhaler Kit and Refill; (iii) August 2, 2000 letter to Len Terra, Chief of the Medi-Cal Drug Program, introducing the private label Astech Peak Flow Meter; and (iv) January 2, 2001 letter to Len Terra, Chief of the Medi-Cal Drug Program, regarding price changes for certain Dey drugs. (Reid Decl., Ex.

29, at DEY-MDL-0105075; Reid Decl., Ex. 32, at DEY-MDL-0105085, 090; Reid Decl., Ex. 34, DEY-LABS-0415539; Reid Decl., Ex. 35, at DEY-BO0018910, 912.)

Plaintiffs' Response: Plaintiffs dispute the relevance and materiality of these facts.

36. Kevin Gorospe testified that he recalled receiving letters with disclosures like the ones in Dey's price notification letters from manufacturers, but was unaware of any contact initiated by Medi-Cal to Dey after Dey sent such letters:

> Q. Did it ever occur that when you passed on one of those letters to Mr. Terra he -- he asked you to subsequently investigate anything bout the company that had sent it?
> A. No, not that I can recall.
> Q. Do you remember any -- any type of letter like this exhibit touching off some type of investigation, whether you did it or not?
> MR. PAUL: Objection to form.
> THE WITNESS: No.

(Reid Decl., Ex. 27, at 688:16-689:3.)

Plaintiffs' Response: Plaintiffs dispute that the letters referred to in this fact are relevant and material to the issues in this case. Defendant's letters did not reveal that their AWPs were inflated:

> Q. Did Dey ever to your knowledge come to the California Department of Health Care Services and tell the Department that it was reporting grossly inflated Average Wholesale Prices on its drugs?
>
> MR. ROBBEN: Objection as to form.
>
> THE WITNESS: No.

(Hanscom Decl. Ex. 18 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 296:16-22.) Plaintiffs further note that at the time of these letters, Dey's price reporting practices were under investigation by the OIG and California Department of Justice, among others, and Dey was aware of that fact. (Hanscom Decl. Ex. 19 (10/30/01 Rice Dep.) at 113-117.)

VI. THE DOJ AWPS

37. In February of 2000, Patrick Lupinetti of the New York State Office of the Attorney General, Medicaid Fraud Control Unit, sent a letter to the Pharmacy Director of the Medi-Cal Benefits Branch of DHS describing the results of an investigation conducted by the United States Deparment of Justice and several state Medicaid Fraud Control Units. (Reid Decl., Ex. 41.) The letter stated that, as a result of the investigation, First DataBank would begin to report revised AWPs based on market prices, rather than prices reported by manufacturers. (*Id.* at CAAG/DHS0072502-03.) Included with the letter was a binder, comparing wholesaler and group purchasing organization prices to published AWPs for several infusion, injection, and inhalation drugs, on a NDC-specific level. (*See id.* at CAAG/DHS0072506.) The binder included pricing information for 14 of the 28 Dey NDCs that remain at issue in this action, as set forth below.)

Acetylcysteine			
NDC	**Wholesale**	**1999 AWP**	**Spread**
49502-0181-04	$25.80	$67.80	162.79%
49502-0181-10	$15.27	$40.26	163.65%
49502-0181-30	$41.97	$110.48	163.24%
49502-0182-04	$31.08	$81.36	161.78%
49502-0182-10	$18.57	$48.66	162.04%
49502-0182-30	$50.64	$133.43	163.49%

Albuterol Sulfate			
NDC	**GPO**	**1999 AWP**	**Spread**
49502-0697-03	$6.00	$30.25	404.17%
49502-0697-33	$7.20	$36.30	404.17%
49502-0697-60	$14.40	$72.60	404.17%
49502-0196-20	$4.00	$14.99	274.75%

Cromolyn Sodium			
NDC	**GPO**	**1999 AWP**	**Spread**
49502-0689-02	$18.15	$42.00	131.40%
49502-0689-12	$36.30	$84.00	131.40%

Metaproterenol			
NDC	**GPO**	**1999 AWP**	**Spread**
49502-0678-03	$6.25	$30.75	392.00%
49502-0676-03	$6.25	$30.75	392.00%

(*Id.* at CAAG/DHS0072510, 512, 524, 553.)

Plaintiffs' Response: Plaintiffs dispute that the chart from NAMFCU included the word "spread". It did not include a percentage of spread, and did not include a column labeled "spread". Defendant Dey has prepared this chart for purposes of this motion.

An accurate depiction of part of the referenced chart from NAMFCU appears below:

ACETYLCYSTEINE

PROD/MFR	NDC	Wholesale	(GPO) DP	1999 AWP Red Book
(Abbott Hosp)				
SOL, IH, 10%,				
30 ml 3s	00074-3307-03	21.90 /MK		34.16
20%, 4 ml				
30 ml 3s	00074-3308-03	18.75 /MK,BB		32.99
(Dey)				
SOL, IH,10%, 4 ml 12s	49502-0181-04	25.80 /MK		67.80
10 ml 3s	49502-0181-10	15.27 /MK		40.26
30 ml 3s	49502-0181-30	41.97 /MK		110.48
20%, 4 ml 12s	49502-0182-04	31.08 /MK		81.36
10 ml 3s	49502-0182-10	18.67 /MK		48.66
30 ml 3s	49502-0182-30	50.64 /MK		133.43
100 ml ea	49502-0182-00	75.90 /MK		92.21
(Spalding)				

(Reid Decl. Ex. 41, CAAG/DHS0072510.)

38. Consistent with the letter referenced above, First DataBank began to publish revised AWPs for these drugs. (Reid Decl., Ex. 42, at i.) NAMFCU strongly urged state Medicaid programs to use these AWPs to calculate reimbursement. (*Id.*)

Plaintiffs' Response: Disputed. Within nine months, HCFA withdrew the DOJ AWPs by written notice to California. "This is to notify you that you should NOT use the Department of Justice (DOJ) data…" (Hanscom Decl. Ex. 24 (Program Memorandum Intermediaries/Carriers Change Request 1447, DHHS HFCA, 11/17/2000).) Plaintiffs further dispute that, First DataBank ever published the revised prices before they were withdrawn. FDB made the revised prices available to the states, but continued publishing the original prices. Some states requested

FDB to continue supplying them with the original prices. (Hanscom Decl. Ex. 20 (OIG Report, Sept 2001 "Medicaid's Use of Revised Average Wholesale Prices,") at 3.) The revised prices had problems, which OIG recognized. Many states expressed concern about the process of updating prices, since First DataBank expressed little interest in updating the revised prices. (*Id*. at 6.) Further, widespread complaints from hemophilia groups, pharmacies, infusion providers, physicians, and drug manufacturers were received by participating states, asserting that the revised prices were inaccurate and too low. (*Id* at 7.)

39. California elected not to calculate Medi-Cal reimbursement by use of the new DOJ AWPs, as they came to be known. In a memo to the Governor's office, DHS advised against implementing the new AWPs because of concerns that the decrease in reimbursement may lead to access problems:

> The Department is concerned that providers affected by the new AWPs may discontinue serving [fee-for-service] Medi-Cal patients if the new prices are implemented. If this occurs, patients would either not have access to these important drugs or patients would be directed to a hospital to obtain them. The Department has already received correspondence from various advocacy groups such as hemophilia organizations and pharmacist organizations (see Attachment A) expressing their serious concerns over the new AWPs.

(Reid Decl., Ex. 43, at CAAG/DHS0076375.)

Plaintiffs' Response: Plaintiffs do not dispute the above statement, but state that Dey has selectively chosen this extract, while other salient reasons were also provided. Plaintiffs further clarify that these new DOJ AWPs were a response to a settlement with First DataBank, after an investigation revealed a pattern of misrepresentations by drug manufacturers of the average wholesale prices and wholesale acquisition costs. (Reid Decl. Ex. 43 at CAAG/DHS0076373.) The other (omitted from SOF 39) reasons are as follows: The new prices for the 400 NDCs were unworkable for several reasons beyond patient access. First, they were based on surveys which included deeply discounted programs resulting in substantially lower prices, some decreased by

as much as 80%. DHS also determined that many of these drugs were administered in doctors' offices, so if providers stopped administering these drugs, patients would go to more expensive hospitals for the drugs. (Reid Decl. Ex. 43 at CAAG/DHS0076375.) Second, because the new DOJ AWPs applied only to FFS (fee for service) Medi-Cal patients, and not those enrolled in Medi-Cal's managed care program, the Medi-Cal Drug Rebate Program would be impacted since there would be two different AWPs used as cost bases for reimbursement, compounding drug rebate disputes from drug manufacturers and affecting rebate collection. (Reid Decl. Ex. 43 at CAAG/DHS0076375.)

Plaintiffs further note that the DOJ AWPs were, at best, a partial and incomplete approach to Medi-Cal reimbursement issues, and that the California Legislature had directed the program to perform a comprehensive study of these issues, which was in the preliminary stages.

Finally, as stated in SOF 38 above, HCFA suspended use of the DOJ AWPs within nine months of DOJ sending them out. (Hanscom Decl. Ex. 24.)

40. In a January 2001 response to a survey conducted by HHS-OIG regarding state Medicaid agencies' use of the DOJ AWPs, Kevin Gorospe confirmed that DHS chose not to implement them for reimbursement purposes because of concerns that the lower payments would cause providers to stop offering services to Medi-Cal beneficiaries. (Reid Decl., Ex. 44, at 558:4-559:8, 571:9-574:6; Reid Decl., Ex. 45, at HHD006-0406-07.)

Plaintiffs' Response: Plaintiffs do not dispute that the statement above refers to one of several reasons for not using the DOJ AWPs. The other reasons include "errors in FDB file," beneficiaries "would go to hospitals," and "RFP for study on dispensing fees will modify reimbursement possibly." (Reid Decl. Ex. 45 at HHD006-0407.) Dr. Gorospe, Chief of the Meid-Cal Pharmacy Policy Unit, ended the survey with several handwritten comments, one of which was "AWP needs to be accurate." (Reid Decl. Ex. 45 at HHD006-0411.)

PLAINTIFF'S STATEMENT OF ADDITIONAL UNDISPUTED FACTS IN OPPOSITION TO DEY'S MOTION FOR PARTIAL SUMMARY JUDGMENT

1. Dey never contacted Medi-Cal after OIG issued its 1996 report "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services." (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 303:3-18.)

2. Accurate AWPs would have given Medi-Cal an accurate reimbursement system which would have saved the taxpayers hundreds of millions of dollars. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 303:19-304:11, 313:19-314:3.)

3. Dey has never given anyone in the California Legislature an explanation of the difference between provider costs and AWPs on Dey's drugs. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 308:2-309:1.)

4. Dey has never provided DHCS with any information stating the difference between Dey's AWPs and provider's actual acquisition costs. (Hanscom Decl. Ex. 22 (9/23/08 Hillblom Dep.) at 348:15-349-11.)

5. No one in the California Legislature has ever accepted or approved any inflated or false AWPs. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 308:2-309:1.)

6. It was never the policy of DHCS to accept false information. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 315:3-5.)

7. It was not the policy of DHCS to over-reimburse. (Hanscom Decl. Ex. 23 (3/19/08 Gorospe Dep.) at 357:16-19, 384:8-13; Hanscom Decl. Ex. 14, (5/6/09 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 610:19-611:5.)

8. In 1999, the California Legislature ordered a study of the reimbursement problem. (Hanscom Decl. Ex. 18 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 237:21 -239:16.)

9. The Myers & Stauffer report took approximately 18 months to complete. The Myers & Stauffer report, received on August 23, 2002, was received too late for the California legislature to use for any legislation in 2002. It was used to some extent in 2004 legislation. (Hanscom Decl. Ex. 18 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 246:8–247:1.)

10. The Medi-Cal program depends on the honesty of the people who participate in the program. (Hanscom Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 309:14-20.)

11. California's open formulary contains over 26,000 NDCs. (Hanscom Decl. Ex. 14 (5/6/09 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 619:17-620:2.)

Dated: December 21, 2009

Respectfully submitted,

EDMUND G. BROWN JR.
Attorney General for the State of California

By: */s/ Rita Hanscom*

NICHOLAS N. PAUL
Supervising Deputy Attorney General
RITA HANSCOM
Deputy Attorney General
Bureau of Medi-Cal Fraud and Elder Abuse
Office of the Attorney General
1455 Frazee Road, Suite 315
San Diego, CA 92108
Telephone: (619) 688-6099
Fax: (619) 688-4200

Attorneys for Plaintiff,
STATE OF CALIFORNIA

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Rita Hanscom
RITA HANSCOM